

LETHAL DRUG ABUSE PREVENTION ACT OF 1998

AUGUST 6, 1998.—Ordered to be printed

Mr. CANADY, from the Committee on the Judiciary,
submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 4006]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 4006) to clarify Federal law to prohibit the dispensing or distribution of a controlled substance for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
The Amendment	1
Purpose and Summary	3
Background and Need for Legislation	4
Hearings	11
Committee Consideration	11
Vote of the Committee	11
Committee Oversight Findings	13
Committee on Government Reform and Oversight Findings	13
New Budget Authority and Tax Expenditures	13
Congressional Budget Office Estimate	13
Constitutional Authority Statement	16
Section-by-Section Analysis and Discussion	16
Agency Views	18
Changes in Existing Law Made by the Bill, as Reported	21
Dissenting Views	24

The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Lethal Drug Abuse Prevention Act of 1998”.

SEC. 2. LETHAL DRUG ABUSE PREVENTION.

(a) **DENIAL OF REGISTRATION.**—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

“(i) **ADDITIONAL GROUND FOR DENIAL OF REGISTRATION—ASSISTED SUICIDE.**—The Attorney General shall determine that registration of an applicant under this section is inconsistent with the public interest if—

“(1) during the 5-year period immediately preceding the date on which the application is submitted under this section, the registration of the applicant under this section was revoked under section 304(a)(4); or

“(2) the Attorney General determines, based on clear and convincing evidence, that the applicant is applying for the registration with the intention of using the registration to take any action that would constitute a violation of section 304(a)(4).”.

(b) **SUSPENSION OR REVOCATION OF REGISTRATION.**—

(1) **IN GENERAL.**—Section 304(a) of the Controlled Substances Act (21 U.S.C. 824(a)) is amended—

(A) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(B) by inserting after paragraph (3) the following:

“(4) has intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance for the purpose of alleviating pain or discomfort (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason.”.

(2) **CONFORMING AMENDMENT.**—Section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) (as redesignated by paragraph (1) of this subsection) is amended by inserting “other” after “such” the first place such term appears.

(c) **PAIN RELIEF.**—Section 304(c) of the Controlled Substances Act (21 U.S.C. 824(c)) is amended—

(1) by striking “(c) Before” and inserting the following:

“(c) **PROCEDURES.**—

“(1) **ORDER TO SHOW CAUSE.**—Before”; and

(2) by adding at the end the following:

“(2) **ASSISTED SUICIDE.**—

“(A) **BURDEN OF PROOF.**—At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the Attorney General shall have the burden of proving, by clear and convincing evidence, that the practitioner’s intent was to dispense or distribute a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual. In meeting such burden it shall not be sufficient to prove that the registrant knew that the use of the controlled substance may increase the risk of death.

“(B) **REQUEST FOR REVIEW BY MEDICAL ADVISORY BOARD ON PAIN RELIEF.**—At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the practitioner may request, within 30 days after the receipt of the order to show cause, that the Medical Advisory Board on Pain Relief review, in accordance with paragraph (3), the administrative record of such proceeding as it relates to subsection (a)(4).

“(3) **MEDICAL ADVISORY BOARD ON PAIN RELIEF.**—

“(A) **IN GENERAL.**—The Attorney General shall by regulation establish a board to be known as the Medical Advisory Board on Pain Relief (referred to in this paragraph as the ‘Board’).

“(B) **MEMBERSHIP.**—The Attorney General shall appoint the members of the Board—

“(i) from among individuals who, by reason of specialized education or substantial relevant experience in pain management, are clinical ex-

perts with knowledge regarding standards, practices, and guidelines concerning pain relief; and

“(ii) after consultation with the American Medical Association, the American Academy of Pain Medicine, the American Pain Society, the American Academy of Hospice and Palliative Medicine, the National Hospice Organization, the American Geriatrics Society, and such other entities with relevant expertise concerning pain relief, as the Attorney General determines to be appropriate.

“(C) DUTIES OF BOARD.—If in accordance with paragraph (2)(B) an applicant or registrant requests a review by the Board of the record of a proceeding under paragraph (1), the Board shall review the administrative record of such proceeding as it relates to subsection (a)(4) and issue to the Attorney General an advisory opinion as to whether the dispensing or distribution of the controlled substance at issue in the proceeding was for the purpose of alleviating pain or discomfort in a manner that does not constitute a violation of subsection (a)(4). The opinion of the Board under this subparagraph shall be part of the administrative record and shall be considered by the Attorney General in determining whether to deny, revoke, or suspend the registration involved.”.

SEC. 3. CONSTRUCTION.

(a) IN GENERAL.—Nothing in this Act or the amendments made by this Act shall be construed to imply that the dispensing or distribution of a controlled substance before the date of enactment of this Act for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual is or is not a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.).

(b) INCORPORATED DEFINITIONS.—In this section, the terms “controlled substance”, “dispense”, and “distribute” have the meanings given those terms in section 102 of the Controlled Substances Act (21 U.S.C. 802).

PURPOSE AND SUMMARY

H.R. 4006, The Lethal Drug Abuse Prevention Act of 1998, will ensure that the federal government in no way authorizes the use of federally controlled substances to kill a human being in a physician assisted suicide. The bill amends the Controlled Substances Act of 1970 (CSA) to provide an important additional ground for denial of a Drug Enforcement Administration (DEA) registration—a necessary precondition for a physician or pharmacist to dispense or distribute federally controlled substances. The additional ground requires the Attorney General to find that a DEA registration of an applicant is inconsistent with the public interest if the registration has been revoked for or has been applied for in order to intentionally dispense or distribute a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual.

Importantly, the bill also affirms for the first time in the Controlled Substances Act the use of federally controlled substances for the legitimate medical purpose of relieving pain and discomfort in palliative care. Under the bill, a registrant is completely insulated from these amendments if the purpose of the dispensing or distribution of a controlled substance is to alleviate pain or discomfort, even if the use of the controlled substance may increase the risk of death, so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason. The bill also provides for the establishment of an advisory medical review board of pain relief experts to offer the DEA recommendations on revocation and suspension cases where pain relief may have caused the patient’s death. H.R. 4006 makes a clear distinction between medical practice that may risk death in the interest of relieving pain and suffer-

ing and a practice that has the ending of the patient's life as its goal.

BACKGROUND AND NEED FOR THE LEGISLATION

Two recent events make this legislation necessary. The State of Oregon, in contravention of medical ethics and already existing CSA and DEA provisions, has legalized the use by physicians of lethal doses of controlled substances in suicide. Second, the Attorney General of the United States ruled on June 5 of this year that such usage is now part of the ordinary practice of medicine in Oregon and, therefore, exempt from CSA and DEA jurisdiction.

To quote Dr. Edmund D. Pellegrino, the director of the Center for Clinical Bioethics at Georgetown University:

These two actions violate the universal condemnation in law and medical ethics of physician assistance in suicide; they sanction unilateral definition by one state of what constitutes ordinary medical practice and medical ethics; they set a precedent which will encourage other states to seek similar exemptions from law and ethics; and they devalue and thus endanger the lives of our vulnerable citizens who are within six months of death.¹

H.R. 4006 reaffirms the prohibition in law and ethics against intentionally bringing about the death of any person, and applies brakes to a socially destructive trend toward physician assisted suicide and euthanasia. The bill also reaffirms the appropriate use of controlled substances in adequate doses to relieve pain and suffering, even if such use unintentionally hastens death. Moreover, by enacting this legislation, the Federal government will avoid setting a precedent that would in any way permit unilateral self-exemption by one state from its responsibilities to Federal law and regulation.

I. OREGON'S DEATH WITH DIGNITY ACT AND THE FEDERAL RESPONSE

Just last year, after a vote of 398–16 in the House and a unanimous vote in the Senate, the President signed the Assisted Suicide Funding Restriction Act of 1997 on April 30, 1997, which ensured no federal funds could ever be used to cause a patient's death. Indeed, President Clinton, in signing the bill, said it “will allow the Federal Government to speak with a clear voice in opposing these practices,” and warned that “to endorse assisted suicide would set us on a disturbing and perhaps dangerous path.”

In a letter responding to the inquiry of Judiciary Committee Chairman Henry J. Hyde, dated November 5, 1997, the Administrator of the Drug Enforcement Agency, Thomas K. Constantine, expressed his determination that physician assisted suicide with the use of federally controlled substances violates the Controlled Substances Act of 1970.² Under the DEA ruling, doctors given the special federal license under the Controlled Substances Act to prescribe federally controlled substances could not prescribe them for the purpose of assisting in a suicide. Constantine agreed with the

¹ Hearing on H.R. 4006, the Lethal Drug Abuse Prevention Act, before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 105th Cong., 2d Sess. (July 14, 1998) (prepared statement of Dr. Edmund D. Pellegrino).

² 21 U.S.C. §§ 801–971.

sentiment of many members of Congress that administering a drug to deliberately cause someone to die is not a “legitimate medical purpose” within the meaning of the Controlled Substances Act.

However, in a letter dated June 5, 1998, Attorney General Janet Reno reversed Mr. Constantine’s decision and stated that physician assisted suicide does not fall under the jurisdiction of the Controlled Substances Act. General Reno concluded that State laws legalizing physician assisted suicide control, even where federally controlled substances are used to facilitate such suicides.

The Controlled Substances Act of 1970, as amended, provides a uniform national standard for the control of potentially dangerous drugs, and a system of enforcement and penalties that is independent of state law. However, some of these drugs can help alleviate pain and treat illness or injury when dispensed under strictly controlled conditions. For that reason, physicians and pharmacists may get a special federal license from the DEA, called a DEA registration, which allows them to prescribe these federally controlled drugs for “legitimate medical purposes.” This was confirmed last November in Administrator Constantine’s letter to Chairman Hyde when Constantine concluded that “delivering, dispensing, or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a legitimate medical purpose.”³

While physicians receive their licenses to practice medicine from state medical boards, they receive this separate DEA registration to prescribe controlled substances from the Federal DEA. Each time a physician orders a controlled substance, he or she must fill out a form in triplicate and one copy goes to the DEA. Under the current statutory scheme of the Controlled Substances Act, physicians must be prepared to explain to DEA officials their use of these drugs, and they lose their registration and even risk criminal penalties if they prescribe such drugs for any purpose other than a “legitimate medical purpose.” In her letter to Chairman Hyde,⁴ Attorney General Janet Reno described the Controlled Substances Act in the following manner:

The CSA is a complex regulatory scheme that controls the authorized distribution of scheduled drugs. Physicians, for example, are authorized to prescribe and distribute scheduled drugs only pursuant to their registration with the DEA, and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The relevant provisions of the CSA provide criminal penalties for physicians who dispense controlled substances beyond “the course of professional practice,” 21 U.S.C. § 802(21), see id. § 841(b), and provide for revocation of the DEA drug registrations of physicians who have engaged either in such criminal conduct or in other “conduct which may threaten the public health and safety,” id. § 823(f).

³Letter from The Honorable Thomas K. Constantine, Administrator of the Drug Enforcement Administration of the United States, to Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives (Nov. 5, 1997).

⁴Letter from The Honorable Janet Reno, Attorney General of the United States, to Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998).

The Attorney General, however, did not address in her letter the existing regulatory requirement that practitioners prescribe federally controlled substances only for a “legitimate medical purpose.” The Act is silent as to whether Congress contemplated that physician assisted suicide was or was not a “legitimate medical purpose.” Notwithstanding the “legitimate medical purpose” requirement, the Attorney General’s letter made no mention of this requirement, nor did it say whether physician assisted suicide is a “legitimate medical purpose.”

II. IMPLICATIONS OF THE ATTORNEY GENERAL’S RULING

The Attorney General’s ruling of June 5, 1998, has potentially adverse consequences both in Oregon, where assisted suicide is explicitly permitted in certain circumstances, and in the other 49 states where it is not. In Oregon, the Attorney General’s ruling commits the Drug Enforcement Administration to a role which it has never had under the CSA—that of regulating assisted suicide as a “legitimate medical practice.” Under her ruling, a DEA registration cannot be denied, revoked or suspended in the case of “a physician who has assisted in a suicide in compliance with Oregon law,” but “adverse action under the CSA may well be warranted” when “a physician fails to comply with state procedures” for assisting suicide.⁵

DEA investigation would therefore focus not on whether controlled substances have been used to take human life, but on whether human life has been destroyed in conformance with Oregon law. In effect, the DEA would help enforce Oregon’s regulatory scheme for assisted suicide. The Committee views this as a sharp departure from the intended purposes of the Controlled Substances Act. This would be true of any policy requiring the federal government to provide access to controlled substances for the purpose of assisting suicides. However, the particulars of the Oregon law raise especially obvious legal and practical questions. Physicians are to assist suicides only in cases where a patient is expected to die in six months⁶ and is not suffering from “a psychiatric or psychological disorder, or depression causing impaired judgment.”⁷ Yet physicians generally concede, and the professional literature confirms, that such predictions of life expectancy are unreliable.

Most physicians are ill-equipped to detect depression in their patients at all, much less determine what level of clinical depression is sufficient to cause “impaired judgment.”⁸ In this context, the chief author of the Oregon Death with Dignity Act has written somewhat chillingly that “depression in itself does not rule out the physician’s assistance” under the Act.⁹ Moreover, these and all

⁵Id.

⁶Or. Rev. Stat. § 127.800, 127.805 (1997).

⁷Or. Rev. Stat. § 127.825 (1997).

⁸Hearing on H.R. 4006, the Lethal Drug Abuse Prevention Act, before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 105th Cong., 2d Sess. (July 14, 1998) (oral statement of Dr. Herbert Hendin). See also, “When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context,” New York State Task Force on Life and the Law (May 1994), 126-8.

⁹See, Cheryl K. Smith, “Safeguards for Physician-assisted Suicide: The Oregon Death with Dignity Act,” in S. McLean (ed.), *Death, Dying and the Law* (Dartmouth Publishing 1996), 69-93 at 75.

other guidelines are governed by a “good faith” standard that protects physicians from civil, professional and criminal liability so long as they believe “in good faith” that they have complied with the guidelines.¹⁰ The law’s confidentiality requirements¹¹ and its provision barring notification of family members without a patient’s express consent,¹² make it likely that the public will be unaware of abuses that do occur. The Oregon law’s defects are serious enough that the only federal court to review that law on its merits found it to violate constitutional guarantees of equal protection.¹³

The governor of Oregon has testified to this Committee that he knows of no state penalties for violating the state guidelines;¹⁴ even an Oregon physician generally acknowledged to have performed active euthanasia without his patient’s consent (still a homicide under Oregon law) was recently declared unprosecutable by state officials because of the climate created by the Oregon law permitting assisted suicide.¹⁵

The Attorney General has said that adverse action by the DEA would also be warranted if a physician assists suicides “in a state that has not authorized the practice under any conditions,” which at present encompasses the other 49 states. In these states as well, since the Attorney General finds no distinct policy on assisted suicide in the Controlled Substances Act, the DEA would presumably be required to enforce whatever the standards of individual state laws may be. This could require the DEA to enforce a patchwork of different state policies across the nation, in contradiction to the CSA’s purpose of establishing a uniform federal standard against the misuse of potentially dangerous drugs. While it is not clear whether the Attorney General would have the DEA look to state controlled substances acts or state laws against assisted suicide for its standards, new questions arise in either case.

III. EXEMPTION IN H.R. 4006 FOR USE OF CONTROLLED SUBSTANCES IN PAIN MANAGEMENT

The professional literature reports that state controlled substances acts, while originally based on the Federal Controlled Substances Act, often also contain “more stringent modifications.”¹⁶ In 1996, the American Medical Association (AMA) testified before this Committee that the failure of most states to expressly permit pain management that may unintentionally hasten death had “generated reluctance among physicians to prescribe adequate pain medication.”¹⁷ This year the AMA testified before the Committee that progress has occurred on this front, but many states still have

¹⁰ Or. Rev. Stat. §127.885 (1997).

¹¹ Or. Rev. Stat. §127.865 (1997).

¹² Or. Rev. Stat. §127.835 (1997).

¹³ See, *Lee v. Oregon*, 891 F.Supp. 1429 (D. Or. 1995), vacated on other grounds, 107 F.3d 1382 (9th Cir. 1997), cert. denied, 118 S.Ct. 328 (1997).

¹⁴ Hearing on H.R. 4006, the Lethal Drug Abuse Prevention Act, before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 105th Cong., 2d Sess. (July 14, 1998) (oral statement of Gov. John Kitzhaber).

¹⁵ See, “Doctor won’t be prosecuted,” *The Bulletin* (Bend, OR), Dec. 11, 1997, p. 7.

¹⁶ See, D. Pisano, “Controlled Substances and Pain Management: Regulatory Oversight, Formularies, and Cost Decisions,” 24 *Journal of Law, Medicine & Ethics* 310-316 at 310 (1996).

¹⁷ Hearing on Assisted Suicide in the United States, before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong., 2d Sess. (April 29, 1996) (statement of Lonnie R. Bristow, M.D., President, American Medical Association).

not changed their laws.¹⁸ Many state laws against assisted suicide, including the law recently enacted in Michigan,¹⁹ lack any provision regarding the legitimacy of aggressive pain control that may unintentionally hasten death.

In contrast, the federal standard contained in H.R. 4006 employs language from the Assisted Suicide Funding Restriction Act of 1997 which the AMA has said “assures patients and physicians alike that legislation opposing assisted suicide will not chill appropriate palliative and end-of-life care.”²⁰ Therefore, for the first time, H.R. 4006 amends the CSA to expressly permit and encourage the use of controlled substances for palliative and end-of-life care. This reaffirmation clarifies for many physicians the fact that they are free to use federally controlled substances properly and adequately, and thus encourage better treatment of pain and suffering. Too many physicians mistakenly fear prosecution and hesitate to treat pain and suffering under the current statutory scheme of the CSA.

Rather than “chilling” the use of controlled substances in relief of pain and suffering as opponents of H.R. 4006 speciously argue, the bill would encourage proper use of controlled substances, empower physicians in the relief of pain and suffering, reassure the general public that such usage is both legally and ethically appropriate, and protect the physician who uses controlled substances to relieve pain and suffering, so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason.

This distinction between intended and unintended hastening of death, based on what is sometimes called the “principle of double effect,” enjoys broad support in codes of medical ethics as well as in the Assisted Suicide Funding Restriction Act of 1997 and many state laws on assisted suicide. In upholding New York’s law against assisted suicide last year, the U.S. Supreme Court noted:

[A] physician who withdraws, or honors a patient’s refusal to begin, life-sustaining medical treatment purposefully intends, or may so intend, only to respect his patient’s wishes and “to cease doing useless and futile or degrading things to the patient when [the patient] no longer stands to benefit from them.” Assisted Suicide in the United States, Hearing before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong., 2d Sess., 368 (1996) (testimony of Dr. Leon R. Kass). The same is true when a doctor provides aggressive palliative care; in some cases, painkilling drugs may hasten a patient’s death, but the physician’s purpose and intent is, or may be, only to ease his patient’s pain. A doctor who assists a suicide, however, “must, necessarily and indubitably, intend primarily that the patient be made dead.” *Id.*, at 367. Similarly, a patient who commits suicide with a doctor’s aid necessarily has the specific intent to

¹⁸ Hearing on H.R. 4006, the Lethal Drug Abuse Prevention Act, before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 105th Cong., 2d Sess. (July 14, 1998) (statement of Thomas R. Reardon, President-elect, American Medical Association).

¹⁹ SB 200, 89th Leg., Reg. Sess. of 1998, 1998 Mich. Pub. Acts.

²⁰ Letter from P. John Seward, Executive Vice-President, American Medical Association, to Senator John Ashcroft (Feb. 12, 1997).

end his or her own life, while a patient who refuses or discontinues treatment might not * * *. Logic and contemporary practice support New York's judgment that the two acts are different, and New York may therefore, consistent with the Constitution, treat them differently.²¹

H.R. 4006 also provides an extra measure of protection for physicians in doubtful cases. The legislation provides for a Medical Review Board on Pain Relief composed of peers to advise the Administrative Law Judge on questions of medical fact. Any physician who believes that a legitimate effort to relieve pain has been misinterpreted by law enforcement officers can convene the Board. Whether the advisory board is convened is purely at the discretion of the physician; such board cannot be convened at the request of the DEA. Such a board is essential in providing protection for physicians who use controlled substances in a manner which is not intended to cause, or assist in causing, the death of an individual for any reason.

IV. INTENDED ENFORCEMENT OF H.R. 4006

As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance. Therefore, the DEA must make use of existing statutory authority under section 876 of the CSA to subpoena records for adequate enforcement of the Act to occur. Under this statutory authority, the DEA can and should regularly subpoena reports of assisted suicide that the Oregon Death with Dignity Act requires be made to Oregon authorities in order for assisting suicide to be legal under Oregon law. The committee intends that this ability to subpoena records be used to determine whether any violations of H.R. 4006 have occurred.

Reports and records required by the Oregon Death with Dignity Act will demonstrate whether federally controlled substances have been intentionally dispensed to assist suicide. Under section §127.855 of the Oregon Revised Statutes, the following must be documented or filed in the patient's medical record:

(1) All oral requests by a patient for medication to end his life in a humane and dignified manner;

(2) All written requests by a patient for medication to end his or her life in a humane and dignified manner;

* * * * *

(7) A note by the attending physician * * * indicating the steps taken to carry out the request, *including a notation of the medication prescribed*. (Emphasis added.)

Under rules issued November 5, 1997 by the Health Division of the Oregon Department of Human Resources:

At the time the attending physician writes a prescription for medication to end life of a qualified patient, the attending physician shall send two documents to the State Registrar * * * : (1) a copy of the patient's written request for medication to end life, as specified in Section 6 of the Act,

²¹ *Vacco v. Quill*, 117 S.Ct. 2293, 2298-9, 2302 (1997).

and (2) a signed and dated report, entitled “Request for Medication to End Life, Attending Physician’s Report and Medical Records Documentation,” * * * which either is (a) fully and accurately completed or (b) indicates that the attending physician agrees to make available the relevant portions of the patient’s medical record for Division review to determine compliance with the Act * * *.²²

Thus, in order to comply with the Oregon Death with Dignity Act and escape criminal liability that would otherwise exist under Oregon law for assisting a suicide, a physician must note the precise medication used to assist a suicide in the patient’s medical record, and must file a form with the State Registrar reporting the provision of that medication. The physician must either list the specific medication in Part G of a two page “Attending Physician’s Compliance Form” or must file a short form identifying the patient and physician together with a commitment “to make available to the Health Division the relevant portions of the patient’s medical record to determine compliance with the Death with Dignity Act.”

The Drug Enforcement Administration has authority to subpoena the reports that must be provided to Oregon authorities, and, if necessary, the corresponding patient’s medical record. Under section 876 of the CSA, “[i]n any investigation * * * with respect to controlled substances, the Attorney General may * * * require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation.”

It is the intent of the committee that at appropriate periodic intervals, on at least a quarterly basis, the DEA subpoena copies of any relevant reports filed with the Oregon State Registrar. These would provide identification of each physician who has provided lethal medication to a patient for the purpose of assisting suicide as permitted by Oregon law, and might identify the medication used. For those physicians who elect the short form that does not identify the medication used, the DEA should then subpoena the relevant medical records directly from the physician to determine whether the lethal medication included any federally controlled substance.

This information, once obtained in response to subpoena, will indicate unequivocally whether a federally controlled substance had been prescribed to assist suicide in violation of the Lethal Drug Abuse Prevention Act. If so, this would be sufficient in itself—without need for further investigation—to provide adequate evidence for the suspension or revocation of the physician’s registration to distribute controlled substances, in accordance with 21 U.S.C. § 824(a) as amended by the Lethal Drug Abuse Prevention Act.²³

It is the intent of the committee that the same regular use of the subpoena power be employed by the DEA in any other state in which assistance of suicide should become legal and in which re-

²² Or. Admin. R. 333-009-0010(1)(a)(1997).

²³ See, 21 U.S.C. § 824(c) for the procedure for such a suspension or revocation, and 21 U.S.C. § 824(d) for the authority to “suspend any registration simultaneously with the institution of proceedings under this section, in cases where [the Attorney General] finds that there is an imminent danger to the public health or safety.”

ports of such assistance must be made, as a matter of state law, to state authorities.

HEARINGS

The Committee's Subcommittee on the Constitution held a hearing on H.R. 4006, the "Lethal Drug Abuse Prevention Act of 1998" on Tuesday, July 14, 1998. Testimony was received from the following witnesses: Herbert Hendin, M.D., Professor of Psychiatry, New York Medical College; John A. Kitzhaber, Governor, State of Oregon; N. Gregory Hamilton, M.D., Physicians for Compassionate Care; Diane Coleman, President, Not Dead Yet; Thomas J. Marzen, General Counsel, National Legal Center for the Medically Dependent & Disabled, Inc.; Calvin H. Knowlton, Ph.D., Pharmacist, American Pharmaceutical Association; Douglas Pisano, Ph.D., Associate Professor of Pharmacy Administration, Division of Pharmaceutical Services, Massachusetts College of Pharmacy and Allied Health Science; Thomas R. Reardon, M.D., President-elect, American Medical Association; Edmund D. Pellegrino, M.D., Center for Clinical Bioethics, Georgetown University Medical Center; Representative James L. Oberstar; Representative Peter A. DeFazio; Representative Tom A. Coburn; Representative Darlene Hooley; Representative Joe Pitts; Representative Elizabeth Furse; and Representative Earl Blumenauer.

COMMITTEE CONSIDERATION

On Wednesday, July 22, 1998, the Subcommittee on the Constitution met in open session and ordered reported the bill H.R. 4006, as amended, by a vote of 6 to 5, a quorum being present. On Tuesday, August 4, 1998, the Committee met in open session and ordered reported favorably the bill H.R. 4006 with amendment by voice vote, a quorum being present.

VOTE OF THE COMMITTEE

1. Mr. Canady offered an amendment which clarifies how the Medical Advisory Board on Pain Relief functions under the bill. The amendment was adopted by a voice vote.

2. Mr. Nadler offered an amendment that would have given the Attorney General discretion on determining whether to deny, revoke, or suspend a registration. The amendment was defeated by a rollcall vote of 8-17.

ROLLCALL VOTE NO. 1

AYES	NAYS
Mr. Frank	Mr. Hyde
Mr. Berman	Mr. McCollum
Mr. Nadler	Mr. Coble
Mr. Scott	Mr. Smith
Mr. Watt	Mr. Gallegly
Ms. Lofgren	Mr. Canady
Ms. Jackson Lee	Mr. Inglis
	Mr. Goodlatte
	Mr. Bryant

Mr. Chabot
 Mr. Jenkins
 Mr. Hutchinson
 Mr. Pease
 Mr. Cannon
 Mr. Rogan
 Mr. Graham
 Ms. Bono

3. Mr. Frank offered an amendment that would have exempted States from the Act if the dispensing or distribution of a controlled substance is lawful under State law. The amendment was defeated by a rollcall vote of 8–14.

ROLLCALL VOTE NO. 2

AYES	NAYS
Mr. Frank	Mr. Hyde
Mr. Berman	Mr. McCollum
Mr. Nadler	Mr. Coble
Mr. Scott	Mr. Smith
Mr. Watt	Mr. Canady
Ms. Lofgren	Mr. Inglis
Ms. Jackson Lee	Mr. Goodlatte
Mr. Rothman	Mr. Bryant
	Mr. Jenkins
	Mr. Pease
	Mr. Cannon
	Mr. Rogan
	Mr. Graham
	Ms. Bono

4. Ms. Jackson Lee offered an amendment that would have allowed physician assisted suicide if the individual wishing to commit suicide consented to the physician's participation in the suicide. The amendment was defeated by a rollcall vote of 7–14.

ROLLCALL VOTE NO. 3

AYES	NAYS
Mr. Frank	Mr. Hyde
Mr. Berman	Mr. McCollum
Mr. Nadler	Mr. Smith
Mr. Scott	Mr. Canady
Mr. Watt	Mr. Inglis
Ms. Jackson Lee	Mr. Goodlatte
Mr. Rothman	Mr. Bryant
	Mr. Jenkins
	Mr. Pease
	Mr. Cannon
	Mr. Rogan
	Mr. Graham
	Ms. Bono
	Ms. Lofgren

5. Mr. Scott offered an amendment that would have exempted registrants using a federally controlled substance for the purpose

of causing, or assisting in causing, the suicide of any individual from any civil or criminal liability under the Controlled Substances Act. The amendment was defeated by a rollcall vote of 6–14.

ROLLCALL VOTE NO. 4

AYES	NAYS
Mr. Berman	Mr. Hyde
Mr. Nadler	Mr. McCollum
Mr. Scott	Mr. Coble
Mr. Watt	Mr. Canady
Ms. Lofgren	Mr. Inglis
Ms. Jackson Lee	Mr. Goodlatte
	Mr. Bryant
	Mr. Jenkins
	Mr. Pease
	Mr. Cannon
	Mr. Rogan
	Mr. Graham
	Ms. Bono
	Mr. Rothman

6. Mr. Scott offered an amendment that would have exempted pharmacists and pharmacies from the amendments made by the bill and the underlying requirements of the Act to check the legitimacy or purpose of a physician's prescription. The amendment was defeated by a voice vote.

7. The amendment in the nature of a substitute, as amended, was adopted by a voice vote.

8. Final Passage. Mr. Hyde moved to report the bill, H.R. 4006, favorably as amended by the amendment in the nature of a substitute to the whole House. The motion was agreed to by voice vote.

COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 2(1)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee reports that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT FINDINGS

No findings or recommendations of the Committee on Government Reform and Oversight were received as referred to in clause 2(1)(3)(D) of rule XI of the Rules of the House of Representatives.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 2(1)(3)(B) of House Rule XI is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 2(1)(3)(C) of rule XI of the Rules of the House of Representatives, the Committee sets forth, with respect to

the bill, H.R. 4006, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, August 6, 1998.

Hon. HENRY J. HYDE,
*Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4006, the Lethal Drug Abuse Prevention Act of 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Mark Grabowicz (for federal costs), Lisa Cash Driskill (for the state and local impact), and Matthew Eyles (for the private-sector impact).

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

H.R. 4006—Lethal Drug Abuse Prevention Act of 1998

Summary: H.R. 4006 would make it a violation of the Controlled Substances Act of 1970 to distribute or dispense a controlled substance to assist in suicide or euthanasia. Persons who violate the bill's provisions could face revocation of their license to prescribe controlled substances. The legislation would direct the Attorney General to establish the Medical Advisory Board on Pain Relief to assist in resolving disputes over the dispensing of controlled substances in certain instances of assisted suicide or euthanasia.

CBO estimates that implementing H.R. 4006 would not result in any significant cost to the federal government. Because enactment of H.R. 4006 could affect direct spending and receipts, pay-as-you-go procedures would apply to the bill; however, CBO estimates that the amounts involved would be less than \$500,000 per year.

H.R. 4006 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would have no impact on the budgets of state, local, or tribal governments. The bill would impose a new private-sector mandate as defined in UMRA, but the direct costs imposed by the mandate would fall well below the statutory threshold established in UMRA (\$100 million in 1996, adjusted annually for inflation).

Estimated cost to the Federal Government: Enacting the bill would increase administrative costs of the Drug Enforcement Administration (DEA) in cases of assisted suicide or euthanasia that involve controlled substances. CBO expects that any such costs, including those relating to the Medical Advisory Board on Pain Relief, would be funded from user fees that are deposited into the diversion control fee account. Such outlays would constitute direct spending. CBO anticipates very few of these cases, however, so the amount of additional spending would be negligible.

If an individual's license to dispense controlled substances is revoked, the DEA could seize any such substances in their possession. Thus, enacting H.R. 4006 could lead to the seizure of more as-

sets and their forfeiture to the United States, but we estimate that any such increase would be less than \$500,000 annually in value. Proceeds from the sale of any such assets would be deposited as revenues into the assets forfeiture fund of the Department of Justice and spent from that fund in the same year. Thus, the change in direct spending from the assets forfeiture fund would match any increase in revenues to that fund.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. Enacting H.R. 4006 could affect both direct spending and receipts, but CBO estimates that any such effects would be less than \$500,000 a year.

Estimated impact on State, local, and tribal governments: H.R. 4006 contains no intergovernmental mandates as defined in UMRA and would have no impact on the budgets of state, local, or tribal governments. Although Oregon citizens voted to legalize doctor-assisted suicide for terminally ill patients, H.R. 4006 would not preempt that law. It only would make it illegal for doctors to assist in suicide or euthanasia using drugs governed by the federal Controlled Substances Act.

Estimated impact on the private sector: H.R. 4006 would impose a new private-sector mandate, as defined in UMRA. The bill would create a federal prohibition against intentionally dispensing or prescribing controlled substances by medical practitioners for the purpose of assisting the suicide or euthanasia of an individual.

Under current law, medical practitioners who are licensed by state medical boards must also register with the Attorney General through the DEA if they intend to dispense or prescribe controlled substances. Practitioners may now lose their federal registration to dispense those substances if the Attorney General, after considering specific factors, determines that the registration would not be in the public interest. Intentionally dispensing or prescribing controlled substances to assist or facilitate a suicide or euthanasia is not included in that list of factors, but under the provisions of H.R. 4006, it would be grounds for suspending or revoking a practitioner's federal license. In addition, controlled substances possessed by practitioners whose licenses have been revoked or suspended based on the bill's provisions would be subject to government seizure.

CBO estimates that direct costs of the mandate on federally registered practitioners in H.R. 4006 would fall well below the statutory threshold in UMRA. In all states except Oregon, it is a crime for medical practitioners to assist in the suicide or euthanasia of an individual. Moreover, one recent study indicates that only a small percentage of physicians who provide care for dying patients—about 6 percent—have actively helped patients die. Thus, the number of medical practitioners potentially affected by the prohibition would be small.

Estimate prepared by: Federal costs: Mark Grabowicz; Impact on State, local, and tribal governments: Lisa Cash Driskill; Impact on the private sector: Matthew Eyles.

Estimate approved by: Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to rule XI, clause 2(1)(4) of the Rules of the House of Representatives, the Committee finds the authority for this legislation in Article I, section 8, clause 3 of the Constitution.

SECTION-BY-SECTION ANALYSIS

SECTION 1. SHORT TITLE

This section provides that this Act may be cited as the “Lethal Drug Abuse Prevention Act of 1998.”

SECTION 2. LETHAL DRUG ABUSE PREVENTION

Section 2 of the Lethal Drug Abuse Prevention Act of 1998 would amend sections 303 and 304 of the Controlled Substances Act (21 U.S.C. §§823, 824) by providing an additional ground for the denial of a DEA registration: the use of or intended use of a DEA registration to engage in physician assisted suicide.

Section 2(a) of the bill directs the Attorney General to find a DEA registration of an applicant to be inconsistent with the public interest if: the registration of the applicant was revoked in the last 5 years for engaging in physician assisted suicide or, the Attorney General determines based on clear and convincing evidence, that the applicant for the DEA registration is applying for the registration to in fact engage in physician assisted suicide in violation of the offense contained in section 2(b).

Section 2(b) contains the operative offense of the Lethal Drug Abuse Prevention Act of 1998 and makes plain that the DEA registration of a physician will be revoked if that physician:

* * * has intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance for the purpose of alleviating pain or discomfort (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason.

Webster’s Third New International Dictionary Unabridged (Merriam-Webster, 1986) defines “suicide” in relevant part as “the act or an instance of taking one’s own life voluntarily and intentionally; self-destruction.” It defines “euthanasia” in relevant part as “the act or practice of painlessly putting to death persons suffering from incurable conditions or diseases.” By “assisted suicide” the Committee intends to describe the provision of any means (including a lethal drug overdose) to another person with the intent of enabling or assisting that person to kill himself or herself (as by ingesting the lethal overdose). It should be emphasized that euthanasia can occur whether or not the person who is killed consents to be killed.

Section 2(b)(1) of H.R. 4006 speaks of purposefully “causing, or assisting in causing, the suicide or euthanasia of any individual,”

and also of purposefully “causing, or assisting in causing, the death of an individual.” The latter phrase does not refer to activity distinct from deliberately assisting in suicide or performing euthanasia. It is used in the legislation for clarification, chiefly because proponents of assisted suicide and euthanasia often use other terms to describe these activities such as “physician-aid-in-dying.” The Oregon Death with Dignity Act, which legalizes assisted suicide under certain circumstances, specifically provides that “[a]ctions taken in accordance with [this law] shall not, for any purpose, constitute assisted suicide, mercy killing, or homicide under the law”²⁴ It is the Committee’s intention to prohibit the dispensing or distribution of controlled substances for assisted suicide or euthanasia, even if an alternative name has been used to evade such legal limitations.

The language of section 2(b)(1) distinguishing deliberate assistance in suicide and euthanasia from legitimate efforts to alleviate pain or discomfort is based on similar language in the Assisted Suicide Funding Restriction Act.²⁵ Specifically, this language is intended to ensure that “the dispensing or distribution of controlled substances for the purpose of alleviating pain or discomfort” are not prohibited or discouraged by H.R. 4006, even if the use of these substances might as an unintended effect “increase the risk of death.”

The Committee acknowledges and endorses current DEA policy that “controlled substances have legitimate clinical usefulness and the prescriber should not hesitate to consider prescribing them when they are indicated for the comfort and well-being of patients.”²⁶ Thus, for example, the administration of morphine for the purpose of alleviating pain does not violate this section of the bill even if its use might risk causing death or shortening life, as an unintended side-effect, by suppressing respiratory functions. This is true “so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason.” A use of controlled substances designed to alleviate pain or discomfort and “also” purposefully to cause death would result in a violation of section 2(b) of H.R. 4006. Moreover, any use of such substances to purposefully cause death to serve some further purpose such as that of ending pain or discomfort (on the pretext, for example, that dead patients feel no pain or discomfort) also would result in a violation of this section.

Section 2(c) of the bill directs the DEA to establish by regulation a Medical Advisory Board on Pain Relief which will be comprised of individuals who, “by reason of specialized education or substantial relevant experience in pain management, are clinical experts with knowledge regarding standards, practices, and guidelines concerning pain relief.” Under section 2(c), the Board is convened by a practitioner who has allegedly dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual. The advisory board can

²⁴ Or. Rev. Stat. 127.880 (1997).

²⁵ Pub. L. No. 105–12 (1997).

²⁶ “Physician’s Manual: An Informational Outline of the Controlled Substances Act of 1970,” U.S. Department of Justice, Drug Enforcement Administration, Revised March 1990, p. 24.

only be convened at the request of the physician, and not at the request of the DEA. In this manner the Advisory Board serves as a shield for the physician which only the physician can invoke. The function of the Board is to issue an advisory opinion as to whether the dispensing or distribution of the controlled substance at issue in the proceeding was for the purpose of alleviating pain or discomfort in a manner that does not constitute a violation of section 2(b) of the Lethal Drug Abuse Prevention Act.

Under section 2(c) of the bill, after the Attorney General serves upon the applicant or registrant an order to show cause based on subsection (a)(4) as to why the registration should not be denied, revoked, or suspended, the practitioner has 30 days after the receipt of the order to show cause to request review by the Medical Advisory Board on Pain Relief. The Board then will review the administrative record of the order to show cause hearing as it relates to subsection (a)(4) and issue an advisory opinion to the Attorney General. The advisory opinion of the Board will only speak to the subject of whether the dispensing or distribution of the controlled substance at issue in the proceeding was for the purpose of alleviating pain or discomfort in a manner that does not constitute a violation of subsection (a)(4). The opinion of the Board then becomes part of the administrative record and it shall be considered by the Attorney General in determining whether to deny, revoke, or suspend the registration at issue.

SECTION 3. CONSTRUCTION

Section 3(a) of the bill states that the amendments made to the CSA under the Lethal Drug Abuse Prevention Act of 1998 shall not be construed to express an opinion whether the dispensing or distribution of a controlled substance before the date of enactment of this Act for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual is or is not a violation of the Controlled Substances Act.

Finally, section 3(b) of the H.R. 4006 incorporates the existing definitions in the Controlled Substances Act for the terms "controlled substance," "dispense," and "distribute."

AGENCY VIEWS

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF LEGISLATIVE AFFAIRS,
Washington DC, August 3, 1998.

Hon. HENRY J. HYDE,
Chairman, Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: As the Committee prepares to consider H.R. 4006, the "Lethal Drug Abuse Prevention Act of 1998," as amended by the Subcommittee on the Constitution, we write to provide the views of the Department of Justice on this bill. We look forward to working with you on this legislation.

The President is opposed to assisted suicide and any Federal support for it. As such, he is open to working with you and other interested Members of Congress on this complex but extremely important issue. Having said this, the Administration believes that

H.R. 4006 represents a flawed approach to the sensitive area of Federal regulation of medicine. We are fully cognizant of the general authority of the Drug Enforcement Administration (DEA) to regulate physicians' activities that facilitate the abuse or diversion of controlled substances. However, we are concerned that the insertion of the DEA into the role of overseer of the practice of medicine in the unique circumstances of suffering, terminally ill patients would inevitably divert agency attention away from the core mission of strictly controlling Schedule I drugs and preventing the abuse, diversion of and trafficking in all scheduled drugs.

Determination of whether a practitioner's conduct which results in a patient's death—either in a specific instance or in general—is “an appropriate means to relieve pain” is far afield from the DEA's role, as envisaged by Congress and as carried out by the agency, under the original legislative rubric of the Controlled Substances Act (CSA). The medical, scientific, ethical, and related aspects of the practice of medicine at the end of life would involve DEA in issues in which it has no particular expertise. The use of a peer review board of pain management experts would lend needed consultation on the merits of any case, but the very necessity for such a board is evidence of the poor fit between the task DEA is being asked to undertake and its central expertise. Moreover, as noted below, the board's insertion in the context of a contested administrative proceeding could well complicate rather than elucidate matters surrounding physician-assisted suicide.

In addition to the above-noted concerns, the proposed revision of the Controlled Substances Act through H.R. 4006 would not necessarily accomplish the intended effect of banning all assisted suicides, as there are several plausible means of assisted suicide or euthanasia that do not involve the use of controlled substances. Typically, a controlled substance is used as a sedative; a non-controlled substance is used to actually bring about death. Thus, the CSA offers at best only a partial fix. If amendments to the CSA force physicians to use non-controlled substances to assist a patient to hasten a desired death, a procedure that would not explicitly be banned by the CSA, it will not save lives, but merely will increase the amount of pain suffered by those taking their lives.

The limitations of this proposed ban on assisted suicide are apparent by examining the plausible scenario of a patient who has legally obtained a controlled substance from a physician for palliative purposes without disclosing an intent to commit suicide. Once that patient has decided to end his or her own life, they would need only to employ the services of a second physician, who would agree to assist in the suicide so long as the patient agrees to self medicate. As long as the second physician does not “dispense or distribute” a controlled substance, it is difficult to imagine how they could be subject to a revocation action under the proposed changes to the CSA. Moreover, if the bill were modified broadly to reach those who merely assist in a suicide, including by providing their patients with truthful information, it would likely invite serious constitutional challenges.

In addition to the foregoing concerns, the proposed bill raises several technical concerns. First, Sec. 2(a) would amend 21 U.S.C. § 823 to require denial of registration, as inconsistent with the pub-

lic interest, of any application for registration that had either been revoked within the preceding five years under § 824(a)(4) or for which there is “clear and convincing evidence” that it is sought “with the intention of using the registration” to assist a suicide or commit euthanasia. This latter provision may be unworkable. We are concerned that it is not practical to determine in advance an applicant’s “intent” as to how he/she will use a registration; much less can this be determined by clear and convincing evidence. Certainly, few if any applicants will seek the controlled registration with assisted suicide as a primary intended use; even fewer would admit as much on an application. For most physicians, whether they use controlled substances for this purpose will depend on the circumstances, which cannot be foreseen in advance.

There is an apparent inconsistency between Sec. 2(a), stating a new basis for action against a practitioner’s registration under § 824(a)(4), and Sec. 2(c), setting forth the responsibility of the new “Medical Advisory Board on Pain Relief” to issue an opinion under new § 824(c)(3)(C)(i). Under the latter, the Board would review, for appropriateness as a means to relieve pain, “any potential action” (as opposed to “intended” action) by an applicant. Review of “potential” action is even more speculative than “intended” action. Moreover, this section does not mention the clear and convincing evidence standard; it is not clear whether a different level of proof is intended.

The new Board would afford a peer review process to any practitioner aggrieved by a show cause order under 21 U.S.C. § 824(c) proposing to take adverse action against a practitioner’s registration in light of physician-assisted suicide. This provision would for the first time inject a regulatory peer review process into the quasi-judicial administrative discipline process. The Board’s opinion would be “admissible” in any show cause hearing, but would it be binding in effect? If the DEA went against the Board’s decision, either in favor of or against the physician, what would be the likely result on appeal? We think this Board—undoubtedly a well-intended innovation designed to give the physician a fair hearing—unnecessarily creates a myriad of difficult issues.

Finally, in Sec. 3, the language includes a statement that the amendment does not imply that the dispensing of a controlled substance before the date of enactment was *not* a violation of the CSA. In light of the Attorney General’s letter of June 5, 1998, to you, concluding that “adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA,” we recommend a neutral construction regarding the effect of this amendment (e.g., “Nothing in this Act or the amendments made by this Act shall be construed to express an opinion as to whether the dispensing or distribution of a controlled substance before the date of enactment of this Act * * *”).

Thank you for this opportunity to provide our views. The Office of Management and Budget has advised that there is no objection

from the standpoint of the Administration's program to the presentation of this report.

Sincerely,

L. ANTHONY SUTIN,
Acting Assistant Attorney General.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

* * * * *

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

SHORT TITLE

SEC. 100. This title may be cited as the "Controlled Substances Act".

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

REGISTRATION REQUIREMENTS

SEC. 303. (a) * * *

* * * * *

(i) *ADDITIONAL GROUND FOR DENIAL OF REGISTRATION—ASSISTED SUICIDE.*—*The Attorney General shall determine that registration of an applicant under this section is inconsistent with the public interest if—*

(1) *during the 5-year period immediately preceding the date on which the application is submitted under this section, the registration of the applicant under this section was revoked under section 304(a)(4); or*

(2) *the Attorney General determines, based on clear and convincing evidence, that the applicant is applying for the registration with the intention of using the registration to take any action that would constitute a violation of section 304(a)(4).*

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) * * *

* * * * *

(4) *has intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance for the purpose of alleviating pain or discomfort (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason;*

[(4)] (5) *has committed such other acts as would render his registration under section 303 inconsistent with the public interest as determined under such section; or*

[(5)] (6) *has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act.*

A registration pursuant to section 303(g) to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 303(g).

* * * * *

[(c) Before]

(c) *PROCEDURES.*—

(1) *ORDER TO SHOW CAUSE.*—*Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecution or other proceedings under this title or any other law of the United States.*

(2) *ASSISTED SUICIDE.*—

(A) *BURDEN OF PROOF.*—*At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the Attorney General shall have the burden of proving, by clear and convincing evidence, that the practitioner's intent was to dispense or distribute a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual. In meeting such burden it shall not be sufficient to prove that the registrant knew that the use of the controlled substance may increase the risk of death.*

(B) *REQUEST FOR REVIEW BY MEDICAL ADVISORY BOARD ON PAIN RELIEF.*—*At any proceeding under paragraph (1), where*

the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the practitioner may request, within 30 days after the receipt of the order to show cause, that the Medical Advisory Board on Pain Relief review, in accordance with paragraph (3), the administrative record of such proceeding as it relates to subsection (a)(4).

(3) MEDICAL ADVISORY BOARD ON PAIN RELIEF.—

(A) IN GENERAL.—*The Attorney General shall by regulation establish a board to be known as the Medical Advisory Board on Pain Relief (referred to in this paragraph as the “Board”).*

(B) MEMBERSHIP.—*The Attorney General shall appoint the members of the Board—*

(i) from among individuals who, by reason of specialized education or substantial relevant experience in pain management, are clinical experts with knowledge regarding standards, practices, and guidelines concerning pain relief; and

(ii) after consultation with the American Medical Association, the American Academy of Pain Medicine, the American Pain Society, the American Academy of Hospice and Palliative Medicine, the National Hospice Organization, the American Geriatrics Society, and such other entities with relevant expertise concerning pain relief, as the Attorney General determines to be appropriate.

(C) DUTIES OF BOARD.—*If in accordance with paragraph (2)(B) an applicant or registrant requests a review by the Board of the record of a proceeding under paragraph (1), the Board shall review the administrative record of such proceeding as it relates to subsection (a)(4) and issue to the Attorney General an advisory opinion as to whether the dispensing or distribution of the controlled substance at issue in the proceeding was for the purpose of alleviating pain or discomfort in a manner that does not constitute a violation of subsection (a)(4). The opinion of the Board under this subparagraph shall be part of the administrative record and shall be considered by the Attorney General in determining whether to deny, revoke, or suspend the registration involved.*

* * * * *

DISSENTING VIEWS

We strongly oppose H.R. 4006. This legislation represents an unnecessary intrusion into the sensitive relationship between terminally-ill patients and their physicians. Regulating the medical profession and deciding which medical practices are, or are not, legitimate has long been within the sole province of the States and their governing medical boards. This legislation would, instead, empower federal bureaucrats to second-guess the considered judgment of patients and physicians. Moreover, by threatening a doctor with a long prison sentence, this bill will have the effect of making death more painful and agonizing by limiting patient access to appropriate palliative care.

It is for these reasons, among others, that the Department of Justice and the American Medical Association strongly opposes the legislation. H.R. 4006 is also opposed by a wide variety of groups that care about protecting the physician-patient relationship and enhance palliative care, such as the American College of Physicians—American Society of Internal Medicine, Americans for Better Care of the Dying, American Pharmaceutical Association, National Hospice Organization, American Geriatrics Society, American Society of Health System Pharmacists, National Chronic Care Consortium, American Society of Clinical Oncology, and American Association for Geriatric Psychiatry.

Last term, the Supreme Court observed in *Washington v. Glucksberg*¹ that “[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.”² While some of the States engaged in the debate have decided to prohibit physician assisted suicide, Oregon is one that has not.³ This legislation would nullify the democratic will of the people of Oregon, as expressed through two ballot referenda. This debate should continue in the States where it belongs. For these and the following reasons, we dissent from H.R. 4006.

1. H.R. 4006 VIOLATES BASIC PRINCIPLES OF FEDERALISM

This legislation raises serious federalism concerns because it inserts the federal government into what has traditionally been a local medical oversight process. Congressman Frank’s amendment, which would have reduced this legislation’s federalism problems by making the provisions of H.R. 4006 inapplicable to registrants in States that have legalized physician assisted suicide, was rejected

¹ 117 S. Ct. 2258 (1997); 1997 U.S. LEXIS 4039.

² 1997 U.S. LEXIS 4038 at 56.

³ In 1994, Oregon voters enacted, through ballot initiative, the “Death with Dignity Act.” In October 1997, the Ninth Circuit Court of Appeals lifted an injunction against the law’s implementation, and in November 1997, the law withstood a repeal effort by a vote of 60%–40%.

on a party line vote.⁴ One of the fundamental tenets of federalism is that the States are free to act as independent laboratories of democracy. In this case, after considerable debate, the people of the State of Oregon decided that terminally-ill people should have the ability to control the time and manner of their death, and the Nation can now look to Oregon to see how well such a law functions.⁵ It is very unfortunate that this legislation was created solely to override the will of the people of Oregon and their ideas of proper public policy and acceptable morality. Furthermore, the bill runs counter to last term's unanimous Supreme Court decisions on physician aid-in-dying.⁶ In those cases, the Court authorized and encouraged the States to engage in meaningful debate and experimentation.⁷ This bill would end the debate that was encouraged by the Court.

In addition, since the legislation creates a Medical Advisory Board on Pain Relief whose members are appointees of the Attorney General, it will inevitably lead to the politicization and federalization of medical standards. Even though the Attorney General will be required to consult with various medical organizations, she will not be required to heed their advice. The personal views of the Attorney General and the President of the United States, neither of whom must be trained medical professionals, will undoubtedly affect the composition of the Board. Instead of leaving the intensely personal decision making that comes at the end of one's life to the two people who know and matter the most—the patient and the physician—politicians will be making these crucial medical choices for them.

A number of this legislation's supporters have previously expressed concerns regarding overturning the will of the people of a State as expressed through a referendum. For example, in Chairman Hyde's comments supporting H.R. 1252, the Judiciary Reform Act of 1998, which creates a special legal process to protect state referenda, he said that "[t]his legislation recognizes that state referenda reflect, more than any other process, the one-person/one-vote system, and seeks to protect a fundamental part of our national foundation."⁸ Yet, the sole purpose of the "Lethal Drug Abuse Prevention Act of 1998" is to nullify an Oregon referendum permitting physician-assisted suicide. There is a fundamental inconsistency involved in supporting legislation protecting state referenda when they eliminate affirmative action or bilingual education in California, but seeking to legislatively overturn referenda which are less popular with the Republican Majority.

⁴The amendment was rejected by a vote of 8 to 14.

⁵The voters of the State of Michigan will also vote on a ballot measure this November to permit physician-assisted suicide.

⁶*Washington v. Glucksberg*, 117 S. Ct. 2258 (1997); *Vacco v. Quill*, 117 S. Ct. 2293 (1997).

⁷Oregon is not the only State to consider physician assisted suicide. Most recently, an advocacy group for doctor-assisted suicide in Michigan has gathered enough signatures to place an initiative on the legality of the practice on ballot this November. The group received more than 261,000 signatures, which is 14,000 more than were necessary to place the binding question on the statewide ballot.

⁸144 Cong. Rec. H2246 (daily ed. April 23, 1998) (statement of Rep. Hyde).

2. H.R. 4006 WOULD SUBJECT PHYSICIANS AND PHARMACISTS TO CRIMINAL LIABILITY FOR PROVIDING NECESSARY PALLIATIVE CARE

Even though this legislation does not create any express criminal penalties, registrants who violate the Lethal Drug Abuse Prevention Act would be subject to criminal penalties under the Controlled Substances Act (“CSA”). There are a number of sections of the CSA which subject registrants to criminal liability. Among the most significant of these sections is §841(a)(1) which makes it “unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance * * * except as authorized” by the Act.

In *United States v. Moore*⁹ the Supreme Court held that “registered physicians can be prosecuted under §841 when their activities fall outside the usual course of professional practice.”¹⁰ The Court said that “the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician’s dispensing authority to the course of his “professional practice.”¹¹ This bill would provide the legislative history and statutory authority necessary for courts to find that physician assisted suicide is outside the bounds of professional practice. Therefore, physicians who use a controlled substance to assist the suicide of a dying patient would not only lose their DEA license, but would be subject to criminal prosecution.

As further evidence that registrants would be subject to criminal liability, we note that under the CSA, the proceedings to deny, revoke, or suspend a registrant’s license are independent of, and not in lieu of, criminal prosecutions or other proceedings.¹² In addition, we note that in order for a prescription to be valid under DEA regulations, it must be issued for a legitimate medical purpose and in the usual course of professional practice.¹³ This legislation would make physician assisted suicide an illegitimate medical purpose for prescribing a controlled substance and would place it outside the scope of usual professional practice. Therefore, prescriptions issued with the intent to assist suicide would be invalid, and they would likely subject physicians and pharmacists to the full penalties of the Controlled Substances Act.

Physicians could even be subject to prosecution as accessories to possession if they issued a prescription for a large dose of narcotics to a dying patient. It is illegal to knowingly or intentionally possess

⁹ 423 U.S. 122 (1975).

¹⁰ Id. at 124.

¹¹ Id. at 140.

¹² See 21 U.S.C. §824(c) (“Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of Title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.”)

¹³ See 21 C.F.R. 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”)

a controlled substance unless such substance was obtained pursuant to a valid prescription or order from a practitioner while acting in the course of his professional practice.¹⁴ Therefore, a physician could be an accessory to possession if his prescription is construed as being invalid or beyond the course of his professional practice.

Furthermore, pharmacists might be exposed to criminal liability if, for example, they directly distribute a large dose of a controlled substance to a physician in a hospital since it is illegal for a registrant "to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person."¹⁵ The pharmacist's liability would hinge upon a determination of whether or not the dispensing of a large dose of narcotics is "authorized by his registration." This bill would likely make such a distribution unauthorized.

Finally, the requirement that the Attorney General prove by "clear and convincing evidence" that the purpose of a registrant's action was to cause, or assist in causing, the death of an individual does not provide registrants with adequate procedural safeguards. The "clear and convincing" standard is far below the "beyond a reasonable doubt" standard and threatens to take away a registrant's license and expose him to potential criminal liability without ever sufficiently proving the registrant's intent in prescribing a controlled substance to his patient. Unfortunately, Mr. Scott's amendment to except registrants from civil or criminal liability under the bill's disruptive second-guessing of palliative care was not accepted.¹⁶

3. H.R. 4006 WOULD SUBSTANTIALLY BURDEN THE EFFECTIVE TREATMENT OF PAIN

The expansion of DEA authority created by this legislation would make doctors reluctant to prescribe drugs like morphine in doses necessary to relieve a patient's pain due to fears that those doses might not constitute a "legitimate medical purpose" in the DEA's judgment. Each patient is unique and responds differently to medicines used for pain management; therefore, the establishment of arbitrary national standards would hinder physicians in their treatment of patients who require larger-than-normal doses of pain killers. Those physicians who decide to prescribe unusually large, but necessary doses would face administrative burdens, the threat of losing their DEA license, the uncertainty and burden of a hearing, and potential criminal liability. As the American Medical Association warned in their testimony opposing the legislation, "we fear the 'real world' consequences of the bill would be to discourage the kind of appropriate aggressive palliative care that can dissuade patients in pain from seeking just such an early death. Recent promising advancements in the care of people at the end of life could be set back dramatically, to the detriment of patient care."¹⁷

This legislation may even have the effect of increasing the incidence of suicide because it will make palliative care less accessible.

¹⁴ See 21 U.S.C. §844(a).

¹⁵ 21 U.S.C. §842(a)(2)

¹⁶ The amendment was rejected by a vote of 6 to 14.

¹⁷ Statement of Thomas R. Reardon, M.D. on behalf of the American Medical Association, Hearing on H.R. 4006 before the Subcommittee on the Constitution, July 14, 1998.

Even though the language of the legislation suggests that physicians will not lose their licenses for administering controlled substances with the intent of reducing pain even when doing so would hasten death, the practical effect of the legislation is that it will make physicians more reluctant to proscribe large doses of painkillers because they will not want to face an administrative hearing or criminal liability. Therefore, some patients will be forced to live in agony, and many of these patients are likely to end their intolerable suffering by killing themselves. This is because other means involving non-controlled substances which are outside the reach of the federal government will still enable physicians and others to assist in a patient's suicide.

Moreover, since the legislation forbids intentionally dispensing or distributing a controlled substance to cause, or assist in causing, the suicide or euthanasia of any individual, H.R. 4006 will dissuade physicians from sharing information with pharmacists about the patient's therapy so that pharmacists will not know the reason the drug is being prescribed and will not be subject to liability. The legislation will decrease the communication among health care providers at the very time when the pharmacist could provide valuable insight on advancements in areas such as pain management therapy. Mr. Scott's amendment which would have exempted pharmacists and pharmacies from the requirements of H.R. 4006 was rejected by a party line vote.

4. H.R. 4006 CREATES ADMINISTRATIVE DIFFICULTIES AND EXCEEDS THE FUNDAMENTAL PURPOSES AND INTENT OF THE CONTROLLED SUBSTANCES ACT

This legislation would establish a new and burdensome oversight mechanism whereby the DEA would be expected to police every prescription that is dispensed by every health care worker, distributor, and manufacturer in the country. It would replace centuries-old medical boards with a federal law enforcement mechanism to oversee the behavior of the medical community. As the Department of Justice noted in their letter to Chairman Hyde in opposition to the legislation, "[t]he medical, scientific, ethical, and related aspects of the practice of medicine at the end of life would involve DEA in issues in which it has no particular expertise. The use of a peer review board of pain management experts would lend needed consultation on the merits of any case, but the very necessity for such a board is evidence of the poor fit between the task DEA is being asked to undertake and its central expertise."¹⁸

Moreover, the DEA could only monitor such activities either by imposing vast new paperwork requirements on all regulated parties or through dramatic new oversight by law enforcement authorities through a network of health care workers reporting each other, the likes of which would be unprecedented and fundamentally destructive to the proper functioning of the practice of medicine.

The legislation also vastly exceeds and distorts the Controlled Substances Act. The CSA was intended to keep legally available

¹⁸Letter from L. Anthony Sutin, Acting Assistant Attorney General, U.S. Department of Justice, to Chairman Henry J. Hyde, House Committee on the Judiciary (August 3, 1998).

controlled substances within lawful channels of distribution and use.¹⁹ Its purpose is to prevent drug trafficking and drug abuse. The CSA was not intended to override state regulation of the medical profession and medical practice, and in fact, the section of the CSA dealing with the denial, revocation, and suspension of a physician's registration to distribute controlled substances accords great deference to the States. For example, among the factors the Attorney General may consider in deciding whether or not to revoke a physician's license are (i) if the doctor has violated any State law dealing with controlled substances, and (ii) if the doctor has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.²⁰ The CSA was never intended to dictate proper medical practice to physicians; rather, the purpose of the CSA is to distinguish doctors from drug traffickers.

H.R. 4006 also substantially limits the Attorney General's discretion under the CSA. Under the CSA, the Attorney General may revoke or suspend a physician's DEA license if she determines that the physician has committed an act inconsistent with the public interest.²¹ In determining the "public interest," the CSA provides a list of factors for the Attorney General to consider.²² However, H.R. 4006 would substantially limit the Attorney General's discretion since it provides that "[t]he Attorney General shall determine that registration of an applicant * * * is inconsistent with the public interest if" the physician has assisted a suicide by proscribing a controlled substance for that purpose.²³ Previously, registration of a physician could be denied if the Attorney General found it would not be in the public interest, and now the legislation would mandate that physician assisted suicide is not in the public interest. Unfortunately, when Mr. Nadler offered an amendment which would have maintained the Attorney General's discretion in determining whether or not the registration of an applicant would be inconsistent with the public interest, it was rejected on a party line vote.²⁴

CONCLUSION

While some of us do not support the practice of physician assisted suicide, we cannot support this legislation. This bill was drafted solely to override the Oregon referenda which legalized physician assisted suicide in that State. While there have certainly been instances in our Nation's history where it was appropriate for federal law to supercede state law, such as in the realm of civil rights where there was a constitutional imperative and need, this is not one of those cases. States have historically regulated the medical profession, and the federal government has no constitutional authority to do so.

¹⁹ See S. Rep. No. 91-613, at 3 (1969).

²⁰ See 21 U.S.C. § 824(a).

²¹ See 21 U.S.C. § 824(a)(4).

²² See 21 U.S.C. § 823.

²³ H.R. 4006, 105th Cong. § 2(a)(i) (1998).

²⁴ The amendment was rejected by a vote of 8 to 17.

Furthermore, we are concerned about the effect this legislation would have on the treatment of pain. If this legislation is enacted, physicians will fear writing a prescription which could trigger a federal oversight process that might ruin their career and throw them in jail. Consequently, they will be extremely reluctant to prescribe the large doses of narcotics which are often required to treat incapacitating levels of pain. Patients will be left to suffer.

Finally, this legislation will be ineffective in ending the practice of physician assisted suicide. To the extent that supporters of this legislation hope to put an end to physician assisted suicide, they will be disappointed once the bill is put into practice. Physicians will still be able to use non-controlled substances to assist suicides.

Because of the ill effects this legislation will have on the well-being of patients and on the rights of the States, we must dissent.

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